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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

OFFICIAL

Appellants: Jawed Asrar and Jean R. Pierre

Serial No.: 09/714,469

Art Unit: 1714

Filed: November 16, 2000

Examiner: T. H. Yoon

For: *POLYMER BLENDS CONTAINING POLYHYDROXYALKANOATES AND
COMPOSITIONS WITH GOOD RETENTION OF ELONGATION*Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Sir:

This is an appeal from the final rejection of claims 50-75 in the Office Action mailed October 9, 2003, in the above-identified patent application. A Notice of Appeal was mailed on January 9, 2004. The Commissioner is hereby authorized to charge \$165.00, the fee for the filing this Appeal Brief for a small entity, to Deposit Account No. 50-1868. An Amendment accompanies this Appeal Brief.

It is believed that no additional fee is required with this submission. However, should an additional fee be required, the Commissioner is hereby authorized to charge the fee to Deposit Account No. 50-1868.

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(1) REAL PARTY IN INTEREST

The real party in interest of this application is, the assignee, Metabolix, Inc., Cambridge, Massachusetts.

(2) RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences known to appellant, the undersigned, or appellant's assignee which directly affects, which would be directly affected by, or which would have a bearing on the Board's decision in this appeal.

(3) STATUS OF CLAIMS ON APPEAL

Claims 50-75 were renumbered due to an error numbering two claims as "66". Therefore, claims 50-76 are now pending and on appeal. Claims 1-41 were canceled in an Amendment mailed November 16, 2000. Claims 42-49 were canceled in an Amendment mailed February 25, 2003. The text of each claim on appeal, as pending, is set forth in an Appendix I to this Appeal Brief.

(4) STATUS OF AMENDMENTS

The claims were last amended in the amendment mailed September 12, 2003. An amendment after final rejection was mailed on January 9, 2004. In the Advisory Action mailed February 6, 2004, the Examiner indicated that this amendment would not be entered but that claims 50-76 would be renumbered. An amendment correcting language in claims 65 and 69 accompanies this Appeal Brief.

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(5) SUMMARY OF THE INVENTION

The claims relate to polymer blends, which include poly-3-hydroxybutyrate-co-4-hydroxybutyrate (P3HB4HB) and a nucleant. Such compositions exhibit ductility, impact strength and aging characteristics improved to an unexpected and unpredictable extent. The P3HB4HB copolymer has a specified percentage of 4HB units. The nucleant can be any nucleant known to be effective in nucleating polyhydroxyalkanoates ("PHAs"), and is preferably, boron nitride. The concentration of nucleant can be any concentration effective for nucleation of PHAs using the nucleant (page 18, lines 7-9). The polymer compositions have favorable and unexpected elongation properties, and can be used in the production of shaped polymeric objects having improved properties that do not diminish over time (page 18, lines 13-14).

Independent claim 50 is directed to a polymer composition, which includes poly-3-hydroxybutyrate-co-4-hydroxybutyrate (P3HB4HB) and a nucleant with no plasticizer, wherein the percentage of 4-hydroxybutyrate (4HB) in the P3HB4HB is between 16% and 99% (page 17, line 20 through page 18, line 6). Claims 51-53, which are dependent on claim 50, define the nucleant as boron nitride (claim 51) and specify levels of the nucleant as being between 0.1 and 20 wt% (claim 52) and 1 and 10 wt% (claim 53) of the composition (page 18, lines 7-11).

Independent claim 54 recites a method of producing a shaped polymeric object comprising melting the composition described in claim 50. The object is made by extrusion, molding, coating, spinning, blowing, thermoforming or calendaring processes or combinations of the processes (page 7, lines 12-15). Claims 55-57 are dependent upon claim 54. Claim 55

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specifies the nucleant as boron nitride, and claims 56 and 57 recite a shaped object made according to claims 54 and 55, respectively.

Independent claim 58 is directed to a polymer composition which includes poly-3-hydroxybutyrate-co-4-hydroxybutyrate (P3HB4HB) and a nucleant with no plasticizer, wherein the nucleant is present at a level of 0.1 wt% of the composition (page 17, line 20 through page 18, line 11). Claim 59 specifies the nucleant of claim 58 as boron nitride (page 18, lines 7-8). Independent claim 60 recites a method of producing a shaped polymeric object comprising melting the composition of claim 58. The object is made by extrusion, molding, coating, spinning, blowing, thermoforming or calendaring processes or combinations of the processes (page 7, lines 12-15). Claims 61-63 are dependent upon claim 60. Claim 61 specifies the nucleant as boron nitride (page 18, lines 7-8), and claims 62 and 63 recite a shaped object made according to claims 60 and 61, respectively.

Independent claim 64 is directed to a polymer composition comprising poly-3-hydroxybutyrate-co-4-hydroxybutyrate (P3HB4HB) and a nucleant with no plasticizer, wherein the composition is capable of forming a film having elongation (page 33, line 28 through page 34, line 2). Claim 65 recites a range between 560% and 1100% for the elongation at break of the composition of claim 64 (page 33 lines 16-24 and page 35, lines 3- 11). Claims 66 and 67 specify the level of nucleant in the composition of claim 64 as being in the range of 0.1 to 20 wt% and 1 to 10 wt%, respectively (page 18, lines 6-11). Independent claim 68 is directed to a method of producing a shaped polymeric object which includes melting the composition of claim 64. Claim 69 recites a range between 560% and 1100% for the elongation at break of the

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composition of claim 68 (page 33 lines 16-24 and page 35, lines 3- 11). Claims 70-73 further limit the level of the nucleant in claims 68 and 69 to between 0.1 and 20 wt% and 1 and 10% of the composition (page 7, lines 12-15). Claim 74 specifies the nucleant of claim 68 as being boron nitride (page 18, lines 7-8). Finally, claims 75-76 are directed to a shaped article made according to the method of claims 68 and 69, respectively.

(6) ISSUES ON APPEAL

The issues presented on appeal are:

- (1) whether claims 50-76 comply with the written description requirement as required by 35 U.S.C. § 112, first paragraph;
- (2) whether claims 65 and 69 are clear and definite as required by 35 U.S.C. § 112, second paragraph; and
- (3) whether claims 50-76 were properly rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,688,582 to Nagaoka et al. in view of JP 4-326932, JP 6-336523 or JP 6157878 A2.

(7) GROUPING OF CLAIMS

Appellants submit that the claims do not stand or fall together.

The claims can be grouped as follows: (1) claims 50-57, (2) claims 58-63, and (3) claims 64-76.

Group 1 claims are directed to a polymer composition which includes a poly-3-hydroxybutyrate-co-4-hydroxybutyrate (P3HB4HB) blend and a nucleant, wherein the percentage of 4-hydroxybutyrate (4HB) in the P3HB4HB is between 16% and 99%; and a

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method of producing a shaped object which includes melting the polymer composition defined in the group 1 claims.

Group 2 claims recite a polymer composition which includes a poly-3-hydroxybutyrate-co-4-hydroxybutyrate (P3HB4HB) blend and a nucleant, wherein the nucleant is present at a level of 0.1 wt% of the composition; and a method of producing a shaped object which includes melting the polymer composition.

Group 3 claims recite a polymer composition which includes a poly-3-hydroxybutyrate-co-4-hydroxybutyrate (P3HB4HB) blend and a nucleant, wherein the composition is capable of forming a film having elongation; and a method of producing a shaped object which includes melting the polymer composition.

All of the groups require a separate analysis as to patentability since they contain different elements.

(8) ARGUMENTS

(a) The Claimed Invention

The claims are directed to polymer compositions in the production of shaped polymeric objects having improved properties, which do not diminish over time.

There has been considerable interest in recent years in the use of biodegradable polymers to address concerns over plastic waste accumulation. Polyhydroxyalkanoate (PHA) biopolymers are thermoplastic polyesters that are very appealing, since they possess certain properties, such as excellent biodegradability and natural renewability, which distinguish them from

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petrochemical-derived polymers. However, widespread use and acceptance of PHAs has been hindered by certain undesirable chemical and physical properties.

For example, PHAs are among the most thermosensitive of all commercially available polymers. As such, the rate of polymer degradation, as measured by a decrease in molecular weight, increases sharply with increasing temperatures, in the range typically required for conventional melt-processing of PHAs into end-products such as films, coatings, fibers etc. An additional limitation of the potential utility of PHA polymers relates to the observation that some polymer characteristics, such as ductility, elongation, impact resistance, and flexibility, diminish over time. This rapid "aging" of certain PHA-derived products is unacceptable for most commercial applications. Thus, the success of PHA as a viable alternative to both petrochemical-derived polymers and to non-PHA biodegradable polymers, depends upon novel approaches to overcome the unique difficulties associated with PHA polymers.

Appellants' claimed compositions relate broadly to compositions for use in the production of PHA-containing materials having wide-ranging properties that can serve to increase the versatility and performance of PHAs for various processing techniques without sacrificing biodegradability. More specifically, the claims relate to polymer compositions that can include a PHA copolymer, which exhibit ductility, impact strength and aging characteristics improved to an unexpected and unpredictable extent.

In addition, the compositions possess properties that are desirable in numerous applications such as extrusion, molding, coating, spinning, blowing, thermoforming and calendaring processes or combinations of such processes. For example, they are advantageous in

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the production of cast and blown films (both oriented and unoriented) for food packaging, grocery, lawn and trash bags, diaper backsheets and agricultural films having improved elongation to break sustainable over extended periods of time. In addition, the compositions are suitable for use in extrusion and injection stretch blow molding operations, for example to prepare oriented bottles having improved impact strength over extended periods of time. Disposable food packaging articles such as tubs and containers, medical goods such as syringes, labware, and patient kits, as well as disposable plates, cups, knives and forks with improved tensile properties can also be made by injection molding operations using the compositions of the invention. The compositions can also be extruded into sheets and thermoformed into food packaging, plates, bowls etc. Finally, the compositions can be melt spun into fibers for threads, ropes, nets as well as disposable nonwovens for medical applications.

(b) Rejections Under 35 U.S.C. § 112

i. Rejection of Claims 50-76 under 35 U.S.C. § 112, first paragraph (written description)

The Legal Standard

An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed. *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention. See,

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e.g. *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000).

The written description requirement prevents an applicant from claiming subject matter that was not adequately described in the specification as filed. New or amended claims, which introduce elements or limitations that are not supported by the as-filed disclosure, violate the written description requirement. While there is no *in haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure (MPEP 2163 I.)

Claims 50-76 Satisfy the Written Description Requirement

The Examiner states that there is no disclosure with respect to the recited poly-3-hydroxybutyrate-co-4-hydroxybutyrate (P3HB4HB) blend. Appellants respectfully submit that this is incorrect. As described above, the claimed composition is based on the blending of two or more polymers. On page 7, lines 23-24, the specification discloses polymer blends as compositions which comprise two or more structurally distinct biodegradable polymers wherein a first polymer in the blend is preferably a PHA. On page 17, lines 20-22, the specification states that the compositions can comprise a **first biodegradable polymer** comprising a poly-3-hydroxybutyrate-co-4-hydroxybutyrate (P3HB4HB), but does not specifically say the word blend. However, since a blend is defined as a composition that includes a PHA, and P3HB4HB is an example of a PHA (Madison, L.L. and Huisman, G.W., *Microbiol. and Mol. Biol. Rev.* 63 (1): 21-53, (1999)), one of ordinary skill in the art would recognize that P3HB4HB can be included in the blends. Furthermore, the use of the language "first biodegradable polymer"

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would lead one to the conclusion that a second polymer is included in the composition, making it a blend.

In summary, the disclosure fully supports the recited poly-3-hydroxybutyrate-co-4-hydroxybutyrate (P3HB4HB) blends in claims 50-76.

ii. Rejection of Claims 65 and 69 under 35 U.S.C. § 112, second paragraph

The Legal Standard

The legal standard for definiteness states that "definiteness of claim language must be analyzed, not in a vacuum, but in light of:

- A) The content of the particular application disclosure
- B) The teachings of the prior art
- C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

In reviewing a claim for compliance with 35 U.S.C. 112, second paragraph, the examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope and therefore, serves the notice function required by 35 U.S.C. 112, second paragraph. See, e.g. *Solomon v Kimberly-Clark Corp.*, 216 F.3d 1372, 1379, 55 USPQ2d 1279, 1283 (Fed.Cir. 2000) (MPEP 2173.02)

The patentable subject matter should be defined with a "reasonable degree of particularity and distinctness". "Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the Examiner might desire." (MPEP 2173.02)

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Claims 65 and 69 Meet the Definiteness Requirement

Claims 65 and 69 are dependent claims which specify the elongation at break of film recited in claims 64 and 68 to be in the range between 560% and 1100% as measured by tensile testing on molded bars (5X2 mm section, 42 mm gauge length, 10 mm:min crosshead speed). Full support for the range of 560%-1100% is found in Examples 24-26 on pages 33-35. With respect to the recited "5x2 mm section, 42 mm gauge length, and 10 mm:min crosshead speed", this would more accurate read "4 mm wide and 20 mm gauge length". No further search would be needed for this amendment, since this is clearly stated in Examples 24-26. An amendment to alter this language, thereby removing the issue from appeal, accompanies this Appeal Brief.

The Examiner states that the recited percent elongation has little probative value absent particular sample. This is incorrect, since all three examples, 24-26, describe tensile testing on dog-bone samples that are 4 mm wide with a 20 mm gauge length. The particular samples are distinctly defined, therefore, the recited range of percent elongation at break has probative value. It is not necessary to include film thickness for the subject matter of these claims to be defined with a reasonable degree of particularity and distinctness.

(c) Rejections Under 35 U.S.C. § 103

i. Rejection of Claims 50-76 under 35 U.S.C. § 103(a) over U.S. Patent No. 5,688,582 to Nagaoka et al. ("Nagaoka") in view of JP 4-326932, JP 6-336523 or JP 6157878

A2.

The Legal Standard

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The law is quite clear that, for the Patent Office to establish a *prima facie* case of obviousness of claimed subject matter, the prior art references relied upon must provide *both* a suggestion to make the claimed invention and a reasonable expectation of success. It is also clear that the whole field of the invention must be considered, including those publications which teach away from the claimed invention. Particularly relevant to the matters under consideration here are the decisions of the Court of Appeals for the Federal Circuit in *In re Dow Chemical*, 5 USPQ2d 1529 (1988) and *In re Vaeck*, 20 USPQ2d 1438 (1991). The *Dow* Court noted that:

The consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success, viewed in light of the prior art.... Both the suggestion and expectation of success must be founded in the prior art, not in the Appellant's disclosure.

In determining whether such a suggestion can fairly be gleaned from the prior art, *the full field of the invention must be considered*: for the person of ordinary skill is charged with knowledge of the entire body of technological literature, including that which might lead away from the claimed invention.... Evidence that supports, rather than negates, patentability must be fairly considered.

5 USPQ 2d at 1531-1532 (Citations omitted, emphasis added).

In *In re Dow Chemical*, a combination of three components forming an impact resistant rubber-based resin was not found to be obvious based upon art disclosing the individual

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components. The court noted that the record had shown that the claimed combination had previously been made, *but did not produce the product desired*. "That there were other attempts, and various combinations and procedures tried in the past, does not render obvious the later successful one.... Recognition of need, and difficulties encountered by those skilled in the field, are classical indicia of unobviousness," *Id.* at 1531 (citations omitted). The Court found that none of the prior art cited by the Appellant and the PTO suggested that any process could be used successfully in this three-component system to produce the product having the desired properties. Further, the Court stated that evidence from an expert expressing skepticism as to the success of the claimed combination before these inventors proved him wrong should be considered. *Id.* at 1532.

Claims 50-76 are not Obvious over Nagaoka in view of JP 4-326932, JP 6-336523 or JP 6157878 A2.

Nagaoka discloses biodegradable filament nonwoven fabrics from polyester compositions. Nagaoka describes the use of nucleants such as boron nitride and the copolymer of 3HB and 4HB, but not a blend of a copolymer of 3HB and 4HB. In addition, Nagaoka does not disclose that the percentage of 4-hydroxybutyrate (4HB) in the P3HB4HB is between 16% and 99%, and in fact, does not disclose any specific percentages of 4HB at all.

JP 6-336523 and JP 4-326932 disclose poly-3-hydroxybutyrate-co-4-hydroxybutyrate (P3HB4HB), but do not teach the use of a nucleant such as boron nitride nor a polymer blend.

No art has been cited that one skilled in the art could extrapolate from the use of a nucleant with a pure copolymer to the use of a nucleant with a copolymer blend, nor that the

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results can be extrapolated from the P3HB4HB copolymer of undefined composition to the claimed copolymer containing between 16 and 99% 4HB.

Therefore, the Japanese applications neither disclose nor lead one to a polymer blend JP 6157878 A2 refers to a composition having a high crystallization rate, which is the opposite of a material having a high elongation rate. Crystalline materials are typically brittle and not given to elongation without breaking. The material described in the Japanese reference is prepared by compounding, not blending a copolyester which could be 3HB. The 3-HB makes up 85-97 mol% and 4-HB makes up the remaining 3-15 mol% of the copolymer. The composition is in the form of particles and further includes 0.5 to 3 wt% BN particles.

This application is representative of the prior art discussed at the top of page 15 of the present application, which is characterized by brittleness and lack of elongation properties. This alone differentiates applicants' claimed composition and leads one away from the combination of a PHA copolymer blend as defined by appellants. However, the claims can be further distinguished over the Japanese application because the current application claims a polymer blend. JP 6157878 A2 neither discloses nor leads one to a polymer blend.

For a *prima facie* showing of obviousness, there must be some suggestion or motivation to combine the references. Nagaoka discloses biodegradable filament nonwoven fabrics from polyester compositions. JP 6-336523 discloses a molded polyester product suited as a medical material or an artificial organ **used in contact with a soft tissue of the living body**. JP 4-326932 teaches a polyester porous film suitable as a medical material through the use of a polymer material having **biocompatibility**. JP 6157878 A2 discloses a resin composition having

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biodegradability, **biocompatibility** and a high crystallization rate. The three Japanese applications disclose polymer compositions that are biocompatible and intended for use in the living body. It is evident that there is no motivation to combine Nagaoka with these applications, because the nonwoven fabric disclosed by Nagaoka does not have these features. For example, one would not look to the technology disclosed by Nagaoka in order to produce a biocompatible polymer composition that was appropriate for use in a living body.

In summary, neither Nagaoka nor the Japanese applications alone, or in combination, would motivate one of ordinary skill in the art to make a blend comprising poly-3-hydroxybutyrate-co-4-hydroxybutyrate (P3HB4HB), nor would there be a reasonable expectation that if one did make a blend comprising P3HB4HB, that it would have the desirable properties of elongation and tensile strength. Therefore, claims 50-76 are not obvious in view of Nagaoka in combination with JP 6336523, JP 4-326932 or JP 6157878 A2.

(9) SUMMARY AND CONCLUSION

Appellants have invented polymer blends, which include two or more structurally distinct PHAs or a non-PHA polymer in addition to the claimed P3HB4HB copolymer, containing a nucleant, that may be used in the production of shaped polymeric objects having improved properties that do not diminish over time. The blends exhibit enhanced ductility, impact strength and aging characteristics. Appellants blends overcome the limitations of PHA compositions that have restricted their widespread industrial utilization.

The rejections under 35 U.S.C. § 112, first paragraph are improper because the specification sufficiently describes the subject matter in the claims. The application relates to

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PHA-containing polymer blends, and poly-3-hydroxybutyrate-co-4-hydroxybutyrate (P3HB4HB) is an example of a PHA that may be used in the blends.

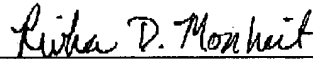
The rejections under 35 U.S.C. § 112, second paragraph are improper, because the claims in question are clear and definite. The recited range of percent elongation at break has probative value and is well-supported in the specification. The subject matter of the claims is defined with a reasonable degree of particularity and distinctness.

Finally, the rejections under 35 U.S.C. § 103 (a) are improper because none of the cited prior art references alone, or in combination, would motivate one of ordinary skill in the art to make a blend comprising poly-3-hydroxybutyrate-co-4-hydroxybutyrate (P3HB4HB) having the defined monomer composition or containing a nucleant as claimed, nor would there be a reasonable expectation that if one did make a blend comprising P3HB4HB, that it would have the desirable properties of elongation and tensile strength.

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For the foregoing reasons, Appellants submit that the claims 50-76, as pending and as amended, are patentable.

Respectfully submitted,



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I hereby certify that this Appeal Brief, and any documents referred to as attached therein are being facsimile transmitted on the date shown below to the Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450.


Brian K. Adams

Date: March 9, 2004

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Appendix I: Claims On Appeal

50. (previously presented) A polymer composition comprising poly-3-hydroxybutyrate-co-4-hydroxybutyrate (P3HB4HB) blend and a nucleant with no plasticizer, wherein the percentage of 4-hydroxybutyrate (4HB) in the P3HB4HB is between 16% and 99%.

51. (previously presented) The composition of claim 50 wherein the nucleant is boron nitride.

52. (previously presented) The composition of claim 50 wherein the nucleant is present at levels between 0.1 and 20 wt% of the blend.

53. (previously presented) The composition of claim 50 wherein the nucleant is present at levels between 1 and 10 wt% of the blend.

54. (previously presented) A method of producing a shaped polymeric object comprising melting a composition comprising a poly-3-hydroxybutyrate-co-4-hydroxybutyrate (P3HB4HB) blend wherein the percentage of 4-hydroxybutyrate (4HB) in the P3HB4HB is between 16% and 99% and a nucleant with no plasticizer, and producing a shaped object therefrom by extrusion, molding, coating, spinning, blowing, thermoforming or calendaring processes or combinations of the processes.

55. (previously presented) The method of claim 54 wherein the nucleant is boron nitride.

56. (previously presented) A shaped object made according to claim 54.

57. (previously presented) A shaped object made according to claim 55.

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58. (previously presented) A polymer composition comprising a poly-3-hydroxybutyrate-co-4-hydroxybutyrate (P3HB4HB) blend and a nucleant with no plasticizer, wherein the nucleant is present at a level of 0.1 wt% of the composition.

59. (previously presented) The composition of claim 58 wherein the nucleant is boron nitride.

60. (previously presented) A method of producing a shaped polymeric object comprising melting a composition comprising a poly-3-hydroxybutyrate-co-4-hydroxybutyrate (P3HB4HB) blend and a nucleant with no plasticizer, and producing a shaped object therefrom by extrusion, molding, coating, spinning, blowing, thermoforming or calendaring processes or combinations of the processes, wherein the nucleant is present at a level of 0.1 wt% of the composition.

61. (previously presented) The method of claim 60 wherein the nucleant is boron nitride.

62. (previously presented) A shaped object made comprising the composition of claim 59.

63. (previously presented) A shaped object made according to claim 60.

64. (previously presented) A polymer composition comprising poly-3-hydroxybutyrate-co-4-hydroxybutyrate (P3HB4HB) blend and a nucleant with no plasticizer wherein the composition is capable of forming a film having elongation.

65. (previously presented) The composition of claim 64 wherein the elongation at break is in the range between 560% and 1100% as measured by tensile testing on molded bars (5X2 mm section, 42 mm gauge length, 10 mm:min crosshead speed).

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66. (previously presented) The composition of claim 64 wherein the nucleant is present at a level between 0.1 and 20 wt% of the composition.

67. (previously presented) The composition of claim 64 wherein the nucleant is present at a level between 1 and 10% of the composition.

68. (previously presented) A method of producing a shaped polymeric object comprising melting a composition comprising a poly-3-hydroxybutyrate-co-4-hydroxybutyrate (P3HB4HB) blend and a nucleant with no plasticizer, and producing a shaped object therefrom by extrusion, molding, coating, spinning, blowing, thermoforming or calendaring processes or combinations of the processes, wherein the composition is capable of forming a film having elongation.

69. (previously presented) The method of claim 68 wherein the elongation at break is in the range between 560% and 1100 as measured by tensile testing on molded bars (5x2 mm section, 42 mm gauge length, 10 mm/min crosshead speed).

70. (previously presented) The method of claim 68 wherein the nucleant is present at a level between 0.1 and 20 wt% of the composition.

71. (previously presented) The method of claim 68 wherein the nucleant is present at a level of 1 to 10% of the composition.

72. (previously presented) The method of claim 69 wherein the nucleant is present at a level between 0.1 and 20 wt% of the composition.

73. (previously presented) The method of claim 69 wherein the nucleant is present at a level of 1 to 10% of the composition.

74. (previously presented) The method of claim 68 wherein the nucleant is boron nitride.

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75. (previously presented) A shaped article made according to the method of claim 68.

76. (previously presented) A shaped article made according to the method of claim 69.

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Appendix II: Claims as Amended

50. (previously presented) A polymer composition comprising poly-3-hydroxybutyrate-co-4-hydroxybutyrate (P3HB4HB) blend and a nucleant with no plasticizer, wherein the percentage of 4-hydroxybutyrate (4HB) in the P3HB4HB is between 16% and 99%.

51. (previously presented) The composition of claim 50 wherein the nucleant is boron nitride.

52. (previously presented) The composition of claim 50 wherein the nucleant is present at levels between 0.1 and 20 wt% of the blend.

53. (previously presented) The composition of claim 50 wherein the nucleant is present at levels between 1 and 10 wt% of the blend.

54. (previously presented) A method of producing a shaped polymeric object comprising melting a composition comprising a poly-3-hydroxybutyrate-co-4-hydroxybutyrate (P3HB4HB) blend wherein the percentage of 4-hydroxybutyrate (4HB) in the P3HB4HB is between 16% and 99% and a nucleant with no plasticizer, and producing a shaped object therefrom by extrusion, molding, coating, spinning, blowing, thermoforming or calendaring processes or combinations of the processes.

55. (previously presented) The method of claim 54 wherein the nucleant is boron nitride.

56. (previously presented) A shaped object made according to claim 54.

57. (previously presented) A shaped object made according to claim 55.

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58. (previously presented) A polymer composition comprising a poly-3-hydroxybutyrate-co-4-hydroxybutyrate (P3HB4HB) blend and a nucleant with no plasticizer, wherein the nucleant is present at a level of 0.1 wt% of the composition.

59. (previously presented) The composition of claim 58 wherein the nucleant is boron nitride.

60. (previously presented) A method of producing a shaped polymeric object comprising melting a composition comprising a poly-3-hydroxybutyrate-co-4-hydroxybutyrate (P3HB4HB) blend and a nucleant with no plasticizer, and producing a shaped object therefrom by extrusion, molding, coating, spinning, blowing, thermoforming or calendaring processes or combinations of the processes, wherein the nucleant is present at a level of 0.1 wt% of the composition.

61. (previously presented) The method of claim 60 wherein the nucleant is boron nitride.

62. (previously presented) A shaped object made comprising the composition of claim 59.

63. (previously presented) A shaped object made according to claim 60.

64. (previously presented) A polymer composition comprising poly-3-hydroxybutyrate-co-4-hydroxybutyrate (P3HB4HB) blend and a nucleant with no plasticizer wherein the composition is capable of forming a film having elongation.

65. (currently amended) The composition of claim 64 wherein the elongation at break is in the range between 560% and 1100% as measured by tensile testing on molded bars (4 mm wide and 20 mm gauge length) (~~5X2 mm section, 42 mm gauge length, 10 mm/min crosshead speed~~).

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66. (previously presented) The composition of claim 64 wherein the nucleant is present at a level between 0.1 and 20 wt% of the composition.

67. (previously presented) The composition of claim 64 wherein the nucleant is present at a level between 1 and 10% of the composition.

68. (previously presented) A method of producing a shaped polymeric object comprising melting a composition comprising a poly-3-hydroxybutyrate-co-4-hydroxybutyrate (P3HB4HB) blend and a nucleant with no plasticizer, and producing a shaped object therefrom by extrusion, molding, coating, spinning, blowing, thermoforming or calendaring processes or combinations of the processes, wherein the composition is capable of forming a film having elongation.

69. (currently amended) The method of claim 68 wherein the elongation at break is in the range between 560% and 1100 as measured by tensile testing on molded bars (4 mm wide and 20 mm gauge length) (~~5x2 mm section, 42 mm gauge length, 10 mm/min crosshead speed~~).

70. (previously presented) The method of claim 68 wherein the nucleant is present at a level between 0.1 and 20 wt% of the composition.

71. (previously presented) The method of claim 68 wherein the nucleant is present at a level of 1 to 10% of the composition.

72. (previously presented) The method of claim 69 wherein the nucleant is present at a level between 0.1 and 20 wt% of the composition.

73. (previously presented) The method of claim 69 wherein the nucleant is present at a level of 1 to 10% of the composition.

74. (previously presented) The method of claim 68 wherein the nucleant is boron nitride.

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75. (previously presented) A shaped article made according to the method of claim 68.

76. (previously presented) A shaped article made according to the method of claim 69.

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